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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,571	10/11/2005	Charles M. Rice III	56029-54474	4463

70119 7590 05/01/2008
THOMPSON COBURN LLP
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

NOTIFICATION DATE	DELIVERY MODE
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05/01/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPDOCKET@THOMPSONCOBURN.COM

Office Action Summary	Application No. 10/534,571	Applicant(s) RICE III ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12-15,33-36 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,12-15,33-36 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 10, 12-15, 33-36, and 39-41 are pending and under consideration.
2. In the prior action, mailed on June 9, 2007, claims 1-38 were under consideration and rejected.
3. In the Response of November 8, 2007, the Applicant amended claims 10, 12, 33-36; cancelled claims 1-9, 11, 16-32, 37, and 38; and added new claims 39-41.

Priority

4. The amendment to the priority, and the petition decision of March 31, 2008 granting the Petition for a Delayed Claim for Priority are noted.

Specification

5. **(Prior Objection- Withdrawn)** The specification was objected to for containing referring to sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). In view of the amendments to the specification, the objection is withdrawn.

Claim Objections

6. It is suggested that claim 10 be amended to indicate in step (a) that the HCV RNA is capable of replication, rather than indicating that it is replicating.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **(Prior Rejection- Withdrawn)** Claims 10-13, 19-36, and 38 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendments to the claims, the rejection is withdrawn.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. **(Prior Rejection- Withdrawn)** Claims 1-38 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for the production of a cell line permissive for HCV replication comprising the culturing of cells comprising a replicating HCV RNA, selecting of cells in which the HCV RNA replicates, and curing the cells of HCV replication, does not reasonably provide enablement for methods of producing cells permissive for HCV replication wherein the cells of the respective steps (a) are infected with or comprise HCV RNA which is merely capable of replication.

The claims were rejected on two grounds.

First, all of the claims were rejected because the claimed methods read on merely infecting or transfecting a cell with HCV RNA and curing the cells of the RNA, without also

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requiring selection of cells in which the HCV RNA is actually capable of replicating. In view of claims 1-9, 11, 16-32, 37, and 38, the rejection is withdrawn from these claims. In view of the amendments to claim 10, including the introduction of a step for obtaining a culture of the cell line that supports HCV RNA replication, whether through use of a genome including a selection gene, or the other means disclosed by the application, the rejection is withdrawn from the remaining claims.

In addition, claims 1-9, 16, 17, and 37 were also rejected for exceeding the scope of enablement because these claims read on methods wherein cells are not transfected with a replicating HCV RNA, but are infected with an HCV virus. In view of the cancellation of these claims, this portion of the rejection is withdrawn.

11. **(Prior Rejection- Withdrawn)** Claims 16, 17, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 16, 17, and 37 were rejected as lacking adequate support for the genus of cells permissive for HCV that are produced by infecting cells with an HCV virus, curing the cells, and identifying sublines of the cured cells that are permissive for HCV. In view of the cancellation of these claims, this portion of the rejection is withdrawn.

It was also indicated that claims 18, 33-36, and 38 were also rejected as lacking adequate support for HCV permissive cells produced by the curing of cells transfected with replicating HCV RNAs (i.e. replicons). In view of the cancellation of claims 18 and 38, and the amendment of claims 33-36 to refer specifically to Huh-7.5 cells, the rejection is withdrawn.

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12. **(New Rejection- Necessitated by Amendment)** Claims 10, 12-15, 33-36, and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are rejected as relying on a **Deposit without a promise for availability**. The deposited cell line identified as ATCC deposit PTA-8561 is required to practice the claimed invention. This is because, the claims require the use of the cell line. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the claimed/described cell line. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the cell line and it is not apparent if it is readily available to the public. Applicant's deposit statement in the abstract of the specification page does not indicate the extent of public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability

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to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

In addition, Applicant is also required to amend the specification in compliance with 37 CFR 1.809(d), so as to identify each of the accession number for the deposit, the date of deposit, a description of the deposited material, and the (complete) name and address of the depository. The present application does not include the complete name and address of the depository.

Claim Rejections - 35 USC § 102-

13. **(Prior Rejection- Withdrawn)** Claims 10-15, 18-36, and 38 were rejected under 35 U.S.C. 102(a) as being anticipated by Blight et al. (J Virol 76: 13001-14). In view of the amendment to the priority, the rejection is withdrawn.

14. **(Prior Rejection- Withdrawn)** Claims 10-15, 18-36, and 38 were rejected under 35 U.S.C. 102(e) as being anticipated by De Francesco et al. (WO 02/059321). In view of the amendments to the claims, the rejection is withdrawn.

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/

Primary Examiner, Art Unit 1648